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| APPLICATION NO.  | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|--|-------------|----------------------|---------------------|------------------|
| 10/089,475   | 08/12/2002  | Joshua W Hamilton    | DC-0190             | 1040             |
| 26259  | 7590        | 03/08/2005           | EXAMINER            |                  |
| LICATLA & TYRRELL P.C.<br>66 E. MAIN STREET<br>MARLTON, NJ 08053 |             |                      | MURPHY, JOSEPH F    |                  |
|  |             |                      | ART UNIT            | PAPER NUMBER     |
|  |             |                      | 1646                |                  |
| DATE MAILED: 03/08/2005  |             |                      |                     |                  |

Please find below and/or attached an Office communication concerning this application or proceeding.

4/L

## Office Action Summary

Application No.

10/089,475

Applicant(s)

HAMILTON ET AL.

Examiner

Joseph F Murphy

Art Unit

1646

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 01 February 2005.  
2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.  
3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 9 is/are pending in the application.  
4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.  
5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.  
6) ☒ Claim(s) 9 is/are rejected.  
7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.  
8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.  
10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  
11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)  
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)  
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_.  
4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.  
5) ☐ Notice of Informal Patent Application (PTO-152)  
6) ☐ Other: \_\_\_\_\_.

## **DETAILED ACTION**

### ***Formal Matters***

Claim 9 is pending and under consideration.

### ***Response to Arguments***

The Declaration under 37 CFR 1.132 filed 11/8/2004 is insufficient to overcome the rejection of claim 9 based upon 35 USC 103(a) as set forth in the last Office action because while the Declaration set forth that B. Moyer, D. Loffing-Cueni, J. Loffing and D. Reynolds did not contribute to the actual invention claimed in the instant application, the instant application still has a different inventive entity than the remaining authorship of the Moyer reference, i.e B.A. Stanton, while the inventors listed on the instant Application are B.A. Stanton and J.W. Hamilton, thus the reference is "by another".

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later

Art Unit: 1646

invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claim 9 stands rejected under 35 U.S.C. 103(a) as being unpatentable over Moyer et al. (1999) in view of Cormack et al. (1996), for reasons of record set forth in the Office Action of 1/29/2004.

Moyer (Moyer BD, Loffing-Cueni D, Loffing J, Reynolds D, Stanton BA. Butyrate increases apical membrane CFTR but reduces chloride secretion in MDCK cells. Am J Physiol. 1999 Aug; 277(2 Pt 2): F271-6) teaches a method of measuring the effect of butyrate on the expression of a CFTR-GFP nucleic acid. The construct comprising CFTR-GFP is set forth on page F272, column 2, third paragraph. The method is set forth on page F274 Figure 3. Moyer et al. does not teach the method using a nucleic acid construct comprising CFTR and eGFP. Cormack et al. (Cormack BP, Valdivia RH, Falkow S. FACS-optimized mutants of the green fluorescent protein (GFP). Gene. 1996; 173(1 Spec No): 33-8) teaches the cloning of GFP mutants which fluoresce more intensely than wild type GFP (page 35, Figure 2). Therefore, it would have been obvious to one of skill in the art at the time the invention was made to practice a method for identifying agents which increase functional cell surface expression of the deltaF508 CFTR protein by exposing cells comprising a genetic construct comprising human CFTR coding sequence and an reporter gene to the agent, measuring expression levels or trafficking of CFTR to the membrane, and comparing the levels of CFTR expression or tracking to controls as taught in the Moyer reference, wherein the reporter gene is eGFP as taught in the Cormack reference. The motivation is provided in the Cormack reference that teaches that eGFP

Art Unit: 1646

has a greatly increased fluorescence intensity, making the mutants useful for a number of applications (page 37, column 2, second paragraph).

Applicant argues that because Moyer et al. is Applicants' own publication which published within the one year grace period allowed under 35 U.S.C. § 102(b) [*sic* (a)], this reference has been improperly cited as basis for rejection under 35 U.S.C. § 103(a). However, the term "others" in 35 U.S.C. 102(a) refers to any entity which is different from the inventive entity. The entity need only differ by one person to be "by others." This holds true for all types of references eligible as prior art under 35 U.S.C. 102(a) including publications as well as public knowledge and use. Any other interpretation of 35 U.S.C. 102(a) "would negate the one year [grace] period afforded under § 102(b)." In re Katz, 687 F.2d 450, 215 USPQ 14 (CCPA 1982). Here, there are other authors listed on the cited publication than are listed as inventors on the instant application, thus the cited reference qualifies as being "by another". Applicant's disclosure of his or her own work within the year before the application filing date cannot be used against him or her under 35 U.S.C. 102(a). In re Katz, 687 F.2d 450, 215 USPQ 14 (CCPA 1982) (discussed below). Therefore, where the applicant is one of the co-authors of a publication cited against his or her application, the publication may be removed as a reference by the filing of affidavits made out by the other authors establishing that the relevant portions of the publication originated with, or were obtained from, applicant. Such affidavits are called disclaiming affidavits. Ex parte Hirschler, 110 USPQ 384 (Bd. App. 1952). The rejection can also be overcome by submission of a specific declaration by the applicant establishing that the article is describing applicant's

Art Unit: 1646

own work. In re Katz, 687 F.2d 450, 215 USPQ 14 (CCPA 1982). It is also possible to overcome the rejection by adding the coauthors as inventors to the application if the requirements of 35 U.S.C. 116, third paragraph are met. In re Searles, 422 F.2d 431, 164 USPQ 623 (CCPA 1970).

### ***Conclusion***

Claim 9 is rejected.

### ***Advisory Information***

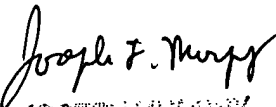
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Joseph Murphy whose telephone number is (571) 272-0877. The examiner can normally be reached Monday through Friday from 7:30 am to 5:00 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tony Caputa, can be reached on (571) 272-0829.

The fax number for the organization where this application or proceeding is assigned is 703-872-9306.

Art Unit: 1646

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Joseph F. Murphy, Ph. D.  
Patent Examiner  
Art Unit 1646  
February 22, 2005

  
JOSEPH MURPHY  
PATENT EXAMINER